K023162
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Fresenius PUNCTUR-GUARD® Fistula Needle Set
510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

MAR 2 0 2003

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Two Ledgemont Center Lexington, MA 02420
Phone:	1-781-402-9785
Fax:	(781) 402-9635
Contact Person:	Nichole Riek, Regulatory Affairs Supervisor
Date of Preparation:	20 December 2002

B. Device Name:

Trade Name:	Fresenius PUNCTUR-GUARD® Fistula Needle Set
Common/Usual Name:	Fistula Needle
Classification Name:	Blood Access Device

C. Predicate Device Name:

The predicate devices for the Fresenius Punctur-Guard Fistula Needle Sets are Bio-Plexus Punctur-Guard Winged Set for Blood Collection (#K003827, 1/8/2001) and the JMS AV Fistula Needle Set "Wing Eater" (#K010406, 6/20/01).

D. Indications for Use:

The Fresenius PUNCTUR-GUARD® Fistula Needle Set is indicated for use as a non-implantable (less than 30 days use) vascular access device for temporary cannulation in procedures requiring an extracorporeal circuit. The set includes a needlestick prevention device using PUNCTUR-GUARD® technology. The features of this device may aid in the prevention of needlestick injury. This device is intended for single use only.

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E. Substantial Equivalence:

1. Is the product a device?

YES - The Fresenius Punctur-Guard Fistula Needle Set is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the Fresenius Punctur-Guard Fistula Needle Set is equivalent to that for the JMS AV Fistula Needle Set "Wing Eater" (#K010406, 6/20/01).

- **Fresenius Punctur-Guard Fistula Needle Set**

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- **JMS AV Fistula Needle Set "Wing Eater"**

Use for temporary cannulation for vascular access for extracorporeal blood treatment. This device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and Wing Eater) aids in prevention of needlestick injury when removing and discarding needle after dialysis session.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The Fresenius Punctur-Guard Fistula Needle Set has been designed to perform equivalently to standard non-blunting fistula needles.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius Punctur-Guard Fistula Needle Set, and demonstrates that it is substantially equivalent to the Bio-Plexus Punctur-Guard Winged Set for Blood Collection and the JMS AV Fistula Needle Set "Wing Eater".

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F. Safety Summary

The Fresenius PUNCTUR-GUARD® Fistula Needle Set will be thoroughly tested and required to meet all final release specifications prior to distribution. The results of design verification indicate that the Fresenius PUNCTUR-GUARD® Fistula Needle Set's performance is equivalent to other fistula needles currently in commercial distribution. The results of this testing, which includes, but is not limited to: sterility, pyrogenicity, physical testing and visual examination of both in-process and finished product, indicate that the device is safe and effective for its intended use. The following testing was performed as part of design verification:

Test	Result
ISO 10993-1 Biocompatibility	Passed
Sheath Removal Force	All samples passed
Penetration Testing	All samples passed
Tubing Tensile Strength	All samples passed
Tubing/Luer Bond Strength	All samples passed
Tubing/Third Wing Bond Strength	All samples passed
Wing Body/Third Wing Disassembly Force	All samples passed
Front Cannula/Wing Body Bond Strength	All samples passed
Blunting Member/Third Wing Bond Strength	All samples passed
Safety Feature Activation Torque Testing	All samples passed
Lock Force – Spring Arm	All samples passed
Positive Pressure Leak Testing	All samples passed
Negative Pressure Leak Testing	All samples passed
Tip to Tip Distance Testing	All samples passed
Rate Flow vs. Pressure Drop	Maximum recommended flow rate for each gauge size: • 17G ≤200 ml/min • 16G ≤300 ml/min • 15G ≤400 ml/min • 14G ≤600 ml/min

In addition, Instructions for Use are provided, which contain instructions for proper use of the device as well as warnings and cautions.

Art Eilinsfeld
Director of Regulatory Affairs

12/22/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Ms. Nichole Riek
Regulatory Affairs Supervisor
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K023162
Trade/Device Name: Fresenius *PUNCTUR-GUARD*® Fistula Needle Set
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 FIE
Dated: December 20, 2002
Received: December 23, 2002

Dear Ms. Riek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius PUNCTUR-GUARD® Fistula Needle Set

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023162